pharmahorizon

A panorama in the world of health sciences

NEWSLETTER FROM DEPARTMENT OF PHARMACY, SUMANDEEP VIDYAPEETH

JUL-SEPT 2016 | Vol II Issue 3

CARTOON

Pharmacy

- Don't take these if you are nursing, pregnant, or about to become pregnant

MANAGING EDITOR'S VIEW

It is my privilege to write a few sentence in the editorial section of Pharmahorizon.

We are successfully publishing this Newsletter since 2015 with the collaboration of our editorial board. This issue gives A tribute to the discoverer of mechanisms for autophagy 'Dr. Yoshinori Ohsumi', who received Nobel Prize in the year 2016. This issue also describes Tafenoquine as Molecule of The Millennium. Which use for the treatment of hypnozoite stages of *Plasmodium vivax* and *Plasmodium ovale*. Which may replace the primaquine because It has the similar mechanism of action.

The section which I found more useful for the readers is "drug safety communication" which highlights the serious adverse effects by the combination of drugs. This time It gives the information that combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths.

In this quarter Department of Pharmacy has organized two day GSPC sponsored refresher course for registered Pharmacists and one day "Continuous Pharmacy Education Program with the theme of "Role of Pharm.D graduates in various health services". We have also celebrated world pharmacist day on 25th September, 2016.

Please enlighten us with your suggestions and contribute for the improvement of pharmahorizon at editorpharmahorizon@gmail.com

Dr. Vikas R Chandrakar, PharmD
Asst. Prof. , DoP, SV

A tribute to the discoverer of mechanisms for autophagy Nobel Prize: 2016

Yoshinori Ohsumi

Ohsumi was born on February 9, 1945 in Fukuoka, Japan. He received a Bachelor of Science (B.Sci.) in 1967 and a Doctor of Science (D.Sci.) in 1974, both from the University of Tokyo. In 1974–77 he was a postdoctoral fellow at the Rockefeller University in New York City.

He returned to the University of Tokyo in 1977 as a Research Associate; he was appointed Lecturer there in 1986, and promoted to Associate Professor in 1988. In 1996, he moved to the National Institute for Basic Biology in Okazaki city, Japan where he was appointed as a Professor. From 2004 to 2009 he was also Professor at the Graduate University for Advanced Studies in Hayama, Japan. In 2009, he transitioned to a three-way appointment as an emeritus Professor at the National Institute for Basic Biology and at the Graduate University for Advanced Studies, and a Professorship at the Advanced Research Organization, Integrated Research Institute, Tokyo Institute of Technology. After his retirement in 2014, he continued to serve as Professor at Institute of Innovative Research, Tokyo Institute of Technology. Currently, he is head of the Cell Biology Research Unit, Institute of Innovative Research, Tokyo Institute of Technology.

Autophagy was already known when he started his career – the term was coined in 1963. During the 1990s, Ohsumi's group described the morphology of autophagy in yeast, and performed mutational screening on yeast cells that identified essential genes for cells to be capable of autophagy.

In 2016, he was awarded the Nobel Prize in Physiology or Medicine for his discoveries of mechanisms for autophagy. He is the 25th Japanese person to win a Nobel Prize.

Source: https://en.wikipedia.org/wiki/Yoshinori_Ohsumi

MOLECULE OF THE MILLENNIUM

TAFENOQUINE

Tafenoquine is an 8-aminoquinoline drug manufactured by Glaxo Smith Kline that is being investigated as a potential drug for treatment of malaria, as well as for malaria prevention.

The proposed indication for tafenoquine is for treatment of the hypnozoite stages of *Plasmodium vivax* and *Plasmodium ovale* that are responsible for relapse of these malaria species even when the blood stages are successfully cleared. This is only now achieved by administration of daily primaquine for 14 days. The main advantage of tafenoquine is that it has a long half-life (2–3 weeks) and therefore a single treatment may be sufficient to clear hypnozoites. The shorter regimen has been described as an advantage.

Like primaquine, tafenoquine causes hemolysis in people with glucose-6-phosphate (G6P) deficiency. Indeed, the long half-life of tafenoquine suggests that particular care should be taken to ensure that individuals with severe G6P deficiency do not receive the drug.

The dose of tafenoquine has not been firmly established, but for the treatment of *Plasmodium vivax* malaria, a dose of 800 mg over three days has been used.

Tafenoquine is a long-acting drug from the same class as primaquine. It has been languishing in development for almost 20 years, but recently there has been a surge of interest in the compound because of its potential to treat *Plasmodium vivax* hypnozoites with a single dose. In a recent multicenter study published in The Lancet a single 300 mg dose of tafenoquine reduced the risk of recurrence within six months of treatment to 10% compared to 60% in those treated with chloroquine alone. Further studies are now in progress to investigate whether tafenoquine is safe and as effective as primaquine. Like primaquine, tafenoquine has potential to cause severe adverse reactions in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency, so it will be important that new tests are developed to screen patients who would need treatment.

Source: https://en.wikipedia.org/wiki/Tafenoquine

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WHO RECOMMENDATIONS

Infant feeding in areas of Zika Virus Transmission

Zika virus is transmitted to humans through the bite of infected *Aedes* mosquitoes. Person-to-person transmission has also been reported from sexual contact, blood transfusion and perinatal transmission. Although the main mode of Zika virus transmission is through infected *Aedes* mosquitoes, current widespread transmission of the virus has raised questions as to whether transmission can also occur during breastfeeding, a practice that is essential to the survival and development of infants and young children.

Interim guidance on breastfeeding in the context of the Zika virus was published by WHO. The recommendations contained in the interim guideline were agreed on through discussion and unanimous consensus by an expert group, which met via teleconference on 19 February 2016. During the discussion with experts, various areas were identified where limited evidence is available and recommendations for further research were made, as well as identifying the need for a systematic review of evidence.

Infants born to mothers with suspected, probable or confirmed Zika virus infection, or who reside in or have travelled to areas of ongoing Zika virus transmission, should be fed according to normal infant feeding guidelines. They should start breastfeeding within one hour of birth, be exclusively breastfed for six months and have timely introduction of adequate, safe and properly fed complementary foods, while continuing breastfeeding up to two years of age or beyond.

Source: http://apps.who.int/iris/bitstream/10665/208875/1/9789241549660_eng.pdf?ua=1

NEW DRUG APPROVAL

Venclexta (venetoclax) for chronic lymphocytic leukemia

The U.S. Food and Drug Administration approved Venclexta (venetoclax) for the treatment of patients with chronic lymphocytic leukemia (CLL) who have a chromosomal abnormality called 17p deletion and who have been treated with at least one prior therapy. Venclexta is the first FDA-approved treatment that targets the B-cell lymphoma 2 (BCL-2) protein, which supports cancer cell growth and is overexpressed in many patients with CLL.

The efficacy of Venclexta was tested in a single-arm clinical trial of 106 patients with CLL who have a 17p deletion and who had received at least one prior therapy. Trial participants took Venclexta orally every day, beginning with 20 mg and increasing over a five-week period to 400 mg. Results showed that 80 percent of trial participants experienced a complete or partial remission of their cancer.

Venclexta is indicated for daily use after detection of 17p deletion is confirmed through the use of the FDA-approved companion diagnostic Vysis CLL FISH probe kit.

The most common side effects of Venclexta include low white blood cell count (neutropenia), diarrhea, nausea, anemia, upper respiratory tract infection, low platelet count (thrombocytopenia) and fatigue. Serious complications can include pneumonia, neutropenia with fever, autoimmune hemolytic anemia, anemia and metabolic abnormalities known as tumor lysis syndrome. Live attenuated vaccines should not be given to patients taking Venclexta.

Source: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm495253.htm

DRUG SAFETY COMMUNICATION

A U.S. Food and Drug Administration (FDA) review has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. Opioids are used to treat pain and cough; benzodiazepines are used to treat anxiety, insomnia, and seizures. In an effort to decrease the use of opioids and benzodiazepines, or opioids and other CNS depressants, together, we are adding Boxed Warnings, our strongest warnings, to the drug labeling of prescription opioid pain and prescription opioid cough medicines, and benzodiazepines.

Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other CNS depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other CNS depressants, including alcohol.

Patients taking opioids with benzodiazepines, other CNS depressant medicines, or alcohol, and caregivers of these patients, should seek medical attention immediately if they or someone they are caring for experiences symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness. Unresponsiveness means that the person doesn't answer or react normally or you can't wake them up. Talk with your health care professional if you have questions or concerns about taking opioids or benzodiazepines.

Opioids are a class of powerful narcotic medicines that are used to treat pain severe enough to warrant use of an opioid when other pain medicines cannot be taken or are not able to provide enough pain relief. They also have serious risks including misuse and abuse, addiction, overdose, and death. Opioids such as codeine and hydrocodone are also approved in combination with other medicines to reduce coughing. Benzodiazepines are a class of medicines that are widely used to treat conditions including anxiety, insomnia, and seizures.

Source: http://www.fda.gov/drugs/drugsafety/ucm518473.htm

DRUGS IN CLINICAL TRIALS

Inovio Pharmaceuticals Doses First Subject in Zika Vaccine Clinical Trial – On July 26, 2016, Inovio Pharmaceuticals, Inc. announced the dosing of the first subject in its multi-center phase I trial to evaluate Inovio's Zika DNA vaccine (GLS-5700). This phase I, open-label, dose-ranging study of 40 healthy adult volunteers is evaluating the safety, tolerability and immunogenicity of GLS-5700 administered with the CELLECTRA®-3P device (Inovio's proprietary intradermal DNA delivery device). In preclinical testing, this synthetic vaccine induced robust antibody and T cell responses – the immune responses necessary to fight viral infections – in small and large animal models.

Source: https://globenewswire.com/news-release/2016/07/26/858976/0/en/Inovio-Pharmaceuticals-Doses-First-Subject-in-Zika-Vaccine-Clinical-Trial.html

Benralizumab Phase III Trials Show Positive Results in Severe Asthma – On September 6, 2016, results from pivotal Phase III trials demonstrated that adding Benralizumab to standard-of-care medicine significantly reduced exacerbations and improved lung function and asthma symptoms in severe asthma patients with an eosinophilic phenotype. The SIROCCO and CALIMA trials evaluated the effect of two dosing regimens of Benralizumab 30 mg administered in 4-week and 8-week regimens as add-on therapy to standard-of-care medicine across primary and key secondary endpoints. Results showed: reductions in the annual rate of asthma exacerbations (up to 51 %), improvement in lung function (change in FEV1 of up to 159 mL) and improvement in asthma symptoms.

Source: http://www.newswire.ca/news-releases/benralizumab-phase-iii-trials-show-positive-results-in-severe-asthma-592415481.html

DIETARY RESEARCH

Diet, Exercise can affect the brain at the molecular level reducing amyloid build up

Modifiable risk factors, such as exercise and consuming a Mediterranean-style diet (MedDiet), can reduce amyloid plaque in patients with mild cognitive impairment (MCI), lowering their risk for conversion to Alzheimer's disease, suggests new imaging research. The small study of 44 participants with MCI or subjective memory impairment (SMI) showed that those with a higher adherence to a MedDiet had significantly lower positron emission tomography (PET) measures of amyloid plaques and tau tangles than those with a lower adherence.

Source: http://www.medscape.com/viewarticle/867787

NEW MOLECULE ENTITY & NEW THERAPEUTIC BIOLOGICAL PRODUCT

Xiidra (Lifitegrast ophthalmic solution)

July 11, 2016 - The U.S. Food and Drug Administration approved Xiidra (Lifitegrast ophthalmic solution) for the treatment of signs and symptoms of dry eye disease. Xiidra is the first medication in a new class of drugs, called lymphocyte function-associated antigen 1 (LFA-1) antagonist, approved by the FDA for dry eye disease.

Source: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm510720.htm

Adlyxin (Lixisenatide)

July 27, 2016 - The U.S. Food and Drug Administration approved Adlyxin (Lixisenatide) a once-daily injection to improve glycemic control (blood sugar levels), along with diet and exercise, in adults with type 2 diabetes. It is a glucagon-like-peptide – 1 (GLP-1) receptor agonist, a hormone helps normalize blood sugar levels.

Source: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm513602.htm

DEPARTMENT OF PHARMACY ACTIVITIES

Refresher course for Registered Pharmacists – Sponsored by Gujarat State Pharmacy Council

A two day refresher course for registered Pharmacists was organized by Department of Pharmacy, Sumandeep Vidyapeeth on 2nd and 3rd July 2016. This program was sponsored by Gujarat State Pharmacy Council, Ahmedabad. The objective of this refresher course was to upgrade the knowledge of Pharmacy Professionals. Further, this workshop also aimed to enrich all the participants about the role of the pharmacist in the responsible use of medicines. Mrs. V. N. Patel, Member, Gujarat State Pharmacy Council was invited as chief guest for the inauguration ceremony of the refresher course. On day 1, Dr. V. B. Patel, Principal, Babaria Institute of Pharmacy, Vadodara delivered the first lecture on topic "Duties of Pharmacists, Prescription Handling & Patient Education". The second plenary lecture was given by Mrs. Aarti Zanwar, Assistant Professor, DoP, SV on topic "Pharmacopoeias". The Speaker for the third session was Mr. Mayur Parmar, Drug Inspector, FDCA, Vadodara, Gujarat. The subject of his presentation was "Drug and Cosmetics Acts & Rules". The last lecture of 1st day was delivered by Dr. Ankur Javia, Assistant Professor, DoP, SV on topic "Immunization – Significance, Schedules & Products available. On day 2, the first talk was given by Dr. R. Balaraman, Professor, DoP, SV on topic "Adverse Drugs Reactions". Further, Dr. A. K. Seth, HoD, DoP, SV delivered a speech on topic "Novel Drug Delivery System: An introduction". The last lecture of the refresher course was given by Dr. Kushal Gohel, Assistant Professor, DoP, SV on topic "Drugs Information for patient counselling". Finally, the refresher course was concluded with the valedictory function in presence of Dr. J. R. Parikh, Member, Gujarat State Pharmacy Council, Ahmedabad.

DEPARTMENT OF PHARMACY ACTIVITIES (CONT.)

Orientation program for Pharm.D students

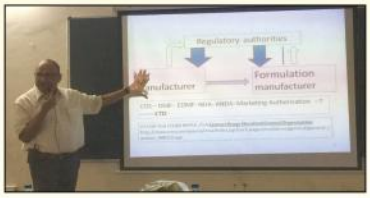
Department of Pharmacy, SV organized an orientation program for first year Pharm.D students on Wednesday, 7th September 2016. Twenty students and their parents attended the program. The aim of conducting orientation program is to prepare students to navigate their new academic environment and to groom and motivate the new entrants to be a good professional. The orientation program educates the new students about the institution, campus and also provides the information about the scope and opportunities of Pharm.D course.

Continuous Pharmacy Education Program

A one day "Continuous Pharmacy Education Program" was organized by Department of Pharmacy, SV on 13th September, 2016. The theme of the program was "Role of Pharm.D graduates in various health services". This program was organized for the purpose of sharing the scope of Pharm.D graduates in various health services such as Pharmacovigilance, Clinical Research and Hospital Management. First session was comprised of three lectures and second session included of poster presentation competition. The session was started with the speech by Dr. Raju Koneri, Dean, Karnataka College of Pharmacy, Bangalore. He delivered a talk on topic "The Role of Pharm.D graduates in Pharmacovigilance". He also explained the scope of Pharm.D graduates in various health services such as Clinical Research. The Speaker for the second plenary lecture was Dr. Vikas Chandrakar, Assistant Professor, DoP, SV. The topic of his lecture was "Role of Pharm.D graduates in clinical research". The last plenary lecture was delivered by Dr. Kushal Gohel, Assistant Professor, DoP, SV. The topic of his presentation was "Role of Pharm.D graduates in Hospital management". At last, the CPE program was concluded with the valedictory function and prize distribution for the poster presentation competition.

Guest lecture on "Regulatory Affairs"

Department of Pharmacy, SV organized a Guest Lecture on "Regulatory Affairs" on 24th September 2016. Dr. N. Sivaramakrishna, Retd. Vice President, Malar Pharmaceuticals, Chennai was invited as an expert to deliver the speech on "Regulatory Affairs". He explained in detail about the importance of Regulatory affairs and the role of regulatory affairs in Pharmaceutical Industry.



World Pharmacist Day Celebration

Department of Pharmacy, SV celebrated world pharmacist day on 25th September, 2016. As a part of celebration, a community awareness program on dengue and chikungunya was organized at Mastupura village and Dhiraj General Hospital. Students of Final B.Pharm, Fourth and Fifth Year Pharm.D participated in the program. Dr. Girish Sailor and Dr. Kushal Gohel were the Co-ordinators of this program. Measurement of blood pressure, body weight, body mass index as well as the history interviews were conducted by the students.

LAUGH & LIVE LONGER

A man goes into a drug store and asks the pharmacist if he can give him something for the hiccups. The pharmacist promptly reaches out and slaps the man's face.
"What did you do that for?" the man asks.
"Well, you don't have the hiccups anymore, do you?"
The man says, "No, but my wife out in the car still does!"

A weeping woman bursts into her hypnotherapist's office and declares, "Doctor, I have been faithful to my husband for 15 years, but yesterday I broke that trust and had an affair! The guilt is killing me. I just want to forget that it ever happened!"
The hypnotherapist shakes his head. "Not again …"

To, ...

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Postal stamp

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